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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,162	11/10/2000	Guillermo J. Tearney	0375.3-1-1	3219

22494 7590 04/07/2006

DALY, CROWLEY, MOFFORD & DURKEE, LLP  
SUITE 301A  
354A TURNPIKE STREET  
CANTON, MA 02021-2714

EXAMINER
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MANTIS MERCADER, ELENI M

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

<b>Office Action Summary</b>	<b>Application No.</b> 09/709,162	<b>Applicant(s)</b> TEARNEY ET AL.	
	<b>Examiner</b> Eleni Mantis Mercader	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed on 1/17/2006 have been fully considered but they are not persuasive.

Applicants' arguments with respect to the obviousness double patenting rejection are not persuasive. The double patenting rejection is with respect to the issued patent to Tearney et al.'003 (US patent No. 6,134,003), which names at least two common inventors: Tearney and Bouma, meeting the requirements of MPEP 804 requiring at least one common inventor. Furthermore, the Examiner correctly applied a secondary reference as prescribed by Form paragraph 8.36.

With respect to the Lennox reference, again the Examiner respectfully disagrees. Lennox teaches a catheter having a catheter body 14 wherein there is a therapeutic laser fiber 15 for treatment and two imaging fibers 32 and 34, thereby defining a multifiber catheter. The fibers are co-axial as indicated by the Examiner in Figure 2A whereby the axis of co-axial arrangement was provided to Applicants under the broadest reasonable interpretation. With respect to the rest of the arguments the Examiner re-instates the prior position as stated below.

The Applicant seems to argue that Boppart et al.'413 does not teach the dispersive element through which energy is transmitted or a focusing element for scanning with wavelengths at different spots or an optical head capable of rotatable or translational movement. The Examiner respectfully disagrees, Boppart et al.'413 clearly teaches the dispersive element which is the transmission fibers (see col. 11, lines 4-7) through which energy is transmitted or in the alternative the interferometer of Boppart et al.'413 is itself a dispersive element as evidenced

Art Unit: 3737

by US Patent No. 5801826, which states that an interferometer is inherently a scanning dispersive element (see col. 3, line 65-col. 4, line 8). Boppart et al.'413 further teaches focusing optical elements such as a lens for scanning with wavelengths at different spots (col. 11, lines 8-10) and an optical head capable of rotatable or translational movement (col. 11, lines 10-12 and see for example figures 4a-b and respective disclosure in col. 11, line 38-col. 12, line 7). With respect to the double patenting rejection, again the Examiner disagrees because claim 1, of the patented claim 1 essentially claims a source, an interferometer and a detector similarly the current claim 1 which claims a source, a dispersive element with focusing capability on impingement spots which is another way of saying an interferometer and a detector. Finally, the Examiner re-directs applicant's attention to col. 11, lines 10-12 and see for example figures 4a-b and respective disclosure in col. 11, line 38-col. 12, line 7 wherein the optical head is capable of rotatable or translational movement. Note that the rotation/translation of the optical head of the fiber is with respect of the body of the catheter. Also, the means plus function language invokes 112 6<sup>th</sup> paragraph.

For the reasons set forth above the rejections are maintained and the rejection is now under Final rejection.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 3737

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Drawings***

2. The drawings are objected to because the boxed elements in Figure 1 are not labeled as to the elements they represent. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 26, 27, 32-35, 48, 55-56, 59-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,134,003 in view of Williams' 826 (US Patent No. 5,801,826). Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent alternate variations and groupings.

The patented claim 1 essentially claims a source, an interferometer and a detector similarly, the current claim 1 claims a source, a dispersive element with focusing capability on

Art Unit: 3737

impringement spots, which is another way of saying an interferometer and a detector. While the claims do not explicitly state that the interferometer is a dispersive element Williams'826 explicitly teaches this in col.3, line 65-col. 4, line 8. Therefore, it would have been obvious to one skilled in the art at the time that the invention was made that an interferometer with a detector is the equivalent of a dispersive element with focusing capability on impringement spots.

***Claim Rejections - 35 USC § 102***

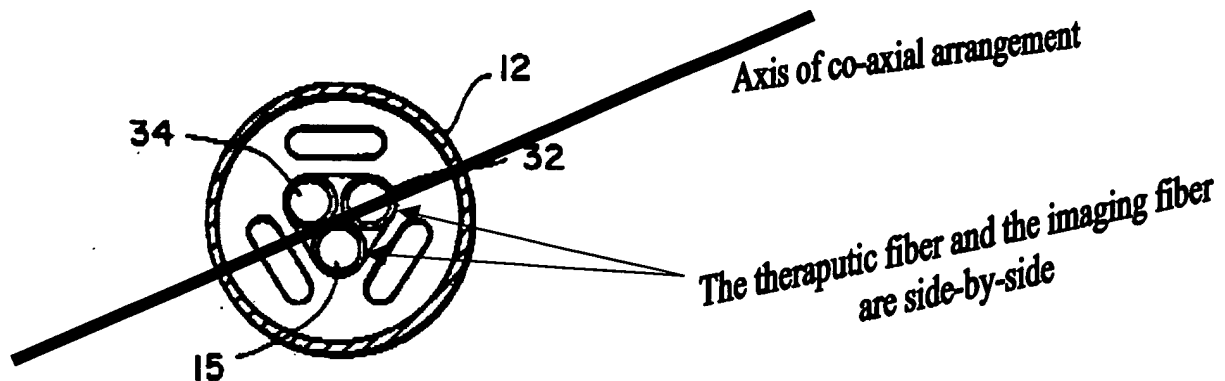
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 48, 50 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Lennox et al.'807 (US Patent No. 5,454,807).

Lennox et al.'807 teaches a catheter having at least one imaging fiber (see fibers 32 and 34 in Figure 2A) and at least one therapeutic light energy delivering fiber (see therapeutic laser delivery fiber 15).



The arrangement of the fibers is co-axial as indicated by the reasonable interpretation of a co-axial axis in Figure 2A. The fibers are arranged next to each other and hence side-by-side as indicated in Figure 2A.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 49, 52, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al.'807.

Lennox et al.'807 teaches treatment of tissues at selected wavelengths depending on the depth of the tissue while imaging (see Figure 2A and col. 5, lines 66-67). It would have been

obvious to one skilled in the art at the time that the invention was made to have used any wavelength capable of treating and imaging at the location of interest and depending on the depth the imaging wavelength could be the same or different from the treating wavelength.

9. Claims 1-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boppart et al.'413 in view of Williams'826.

Boppart et al.'413 teach all the features of the instant invention including a high resolution imaging apparatus having a single or multiple optical fiber system being disposed into a catheter and having lens capable of focusing energy and having detection fibers providing interferometric spectroscopic information (see col. 2, lines 30-67; col. 3, lines 1-27; and see col. 5, lines 3-67; cols. 6-7; and col. 8, lines 1-18). Various modifications such as type of procedures and types of catheters utilizing the optical imaging system are well known modifications to skilled artisans, further more Boppart et al.'413 teaches adaptations of the optical imaging system in a variety of therapeutic surgical instruments as illustrated in Figures 25a-27. With respect to one of the fibers being used for therapeutic purposes, Boppart et al.'413 teaches use of the imaging fibers in a laser based atherectomy catheters (see col. 10, lines 60-62). Therefore, necessarily one of the fibers will be for therapy.

Boppart et al.'413 teaches the dispersive element which is the transmission fibers (see col. 11, lines 4-7) through which energy is transmitted and focusing optical elements such as a lens for scanning with wavelengths at different spots (col. 11, lines 8-10) and an optical head capable of rotatable or translational movement (col. 11, lines 10-12 and see for example figures 4a-b and respective disclosure in col. 11, line 38-col. 12, line 7). Note that the rotation/translation of the optical head of the fiber is with respect of the body of the catheter.



While Boppart et al.'413 does not explicitly state that the interferometer is a dispersive element, Williams'826 explicitly teaches this in col.3, line 65-col. 4, line 8. Therefore, it would have been obvious to one skilled in the art at the time that the invention was made that an interferometer with a detector is the equivalent of a dispersive element with focusing capability on impringement spots.

10. Claims 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boppart et al.'413 in view of Williams'826 as applied above, and further in view of Benja-Athon'052 (US Patent No. 5,843,052).

Boppart et al.'413 in view of Williams'826 do not explicitly teach a kit having an anesthetic and a disinfectant. In the same field of endeavor, Benja-Athon'052 teaches a therapeutic kit which includes an anesthetic and a disinfectant. It would have been obvious to one skilled in the art at the time that the invention was made to have used the device of Boppart et al.'413 in a therapeutic kit along with the required for therapy anesthetic and a disinfectant as taught by Benja-Athon'052 if the therapy of interest required optical imaging in order to monitor the therapy of interest.

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 3737

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is (571) 272-4740. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eleni Mantis Mercader  
Primary Examiner  
Art Unit 3737

EMM